510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Nadine Nasr, RAC Regulatory Affairs Phone Number: 408-523-7093 Fax Number: 408-523-8907 Email: Nadine.nasr@intusurg.com
Date Summary Prepared:	January 17, 2014
Trade Name:	*EndoWrist*® Vessel Sealer
Common Name:	System, surgical, computer controlled instrument
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Codes:	NAY (System, Surgical, Computer Controlled Instrument)
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	*EndoWrist*® *One* Vessel Sealer (K130266, August 29, 2013 and K110639, December 28, 2011)

Device Description

The *EndoWrist* Vessel Sealer is a sterile, single-use (disposable), 8 mm instrument with an integrated cord that connects to the instrument housing and an Erbe VIO dV generator. The *EndoWrist* Vessel Sealer device consists of a distal wristed end effector and a proximal housing connected by a tubular shaft. The housing contains mechanisms to actuate the end effector when attached to the *da Vinci* Model IS4000 Surgical System. An integrated cord attached to the housing is connected to a receptacle in the IESU. An electrode sealing surface and a cutting blade within the jaws of the instrument enable sealing of vessels and cutting of sealed vessels and other tissues. The sealing and cutting functions are controlled using the *da Vinci* Model IS4000 Surgical System foot pedals.

A slider on the housing allows the user to manually open and close the instrument jaws for intraoperative cleaning and grip release. A lock button on the housing allows the user to hold the jaws open for intraoperative cleaning. Two release buttons on the housing allow removal of the Vessel Sealer from the sterile adapter on the *da Vinci* Model IS4000 System instrument arm.

The ERBE VIO dV generator provides the high frequency (radio frequency) electrical current for tissue sealing.

Intended Use/Indications for Use:

The *EndoWrist* Vessel Sealer is a bipolar electrosurgical instrument for use with the *da Vinci* Model IS4000 Surgical System and the ERBE VIO *dV* electrosurgical generator. It is intended for grasping and blunt dissection of tissue and for bipolar coagulation and mechanical transection of vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument. The *EndoWrist* Vessel Sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

Technological Characteristics:

The Intuitive Surgical *EndoWrist* Vessel Sealer is equivalent to the predicate device, the *EndoWrist*® *One* Vessel Sealer, in terms of intended use, indications for use, and technological characteristics. Modifications from the predicate include new features and changes in the functional design of the back end and instrument tip. The changes to the instrument tip do not substantively change the function of the subject device relative to the function of the predicate device.

Performance Data:

Performance test data (bench, animal and cadaver tests and human factors assessment) demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. The testing conducted consisted of

dimensional measurements, mechanical and functional verification, electrical safety, simulated use in animal and cadaver models and human factors assessment as follows:

Bench Testing
Design verification testing of the *EndoWrist* Vessel Sealer (subject device) was performed on an IS4000 *da Vinci* Xi Surgical System. Architectural and functional requirements (e.g., physical dimension, range of motion, cutting/dissecting capabilities, creepage and clearance, force withstand, intuitive motion, electrical, programming, and general features) were tested.

Reliability testing was conducted on the subject device to confirm the requirement for the disposable instrument to withstand use over its useful life (single use).

Burst pressure testing was conducted on the device to demonstrate that the subject device, *EndoWrist* Vessel Sealer, has seal performance on tissue bundles comparable to the predicate device, the *EndoWrist One* Vessel Sealer, and that the subject device effectively transects tissue bundles.

Animal and Cadaver Testing
A series of tests were performed using simulated clinical models (animal) to evaluate the performance of the *EndoWrist* Vessel Sealer (subject device). This included clinical validation to confirm the device meets the user needs and intended use.

A porcine model was utilized in clinical validation testing to provide a test model with similar characteristics to human tissue and a similar abdominal cavity for evaluation of tissue effect and tissue interaction. Testing was done at normal systolic blood pressure levels. Simulated pelvic and gynecologic, renal and upper GI surgical procedures were performed during testing.

In-vivo tissue bundle testing was also conducted to assess the device seal and transection performance on tissue bundles and to demonstrate that the subject device has seal performance comparable to the predicate device, the *EndoWrist One* Vessel Sealer.

A living animal model was utilized for tissue bundle testing because it was necessary to perform the surgery where tissue consistency, bleeding vessels, beating hearts, etc., simulate what will be encountered in human patients. The porcine model provides effective simulation of tissue characteristics of a human specimen.

Human Factors Evaluation
A Human Factor (HF) engineering process was followed in accordance with FDA guidelines for medical devices:

- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, 2000
- Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design, 2011

The human factors engineering process focused on identifying critical tasks and ensuring the safe and effective use of the *EndoWrist* Vessel Sealer device.

A summative usability validation study was conducted with sixteen (16) teams of users (Surgeons and Operating Room (OR) staff). The study was conducted in a simulated operating room (OR) and involved representative typical workflow scenarios as well as certain troubleshooting scenarios that encompassed safety-critical tasks. The *EndoWrist* Vessel Sealer (subject device) training material and user manual were developed in concert with the products and were incorporated in the validation study. The study assessed the following:

- ensure intended users could perform essential and high risk tasks in the expected use environments in a safe and effective manner;
- validate that use-related risks have been mitigated to acceptable levels of residual risk;
- assess the overall ease of use and usability of the *EndoWrist* Vessel Sealer; and
- evaluate whether the design introduced any previously unknown use-related risks.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the Intuitive Surgical *EndoWrist* Vessel Sealer, is substantially equivalent to the predicate device, the Intuitive Surgical *EndoWrist One* Vessel Sealer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 5, 2014

Intuitive Surgical Incorporated
Ms. Nadine Nasr, RAC
Regulatory Affairs
1266 Kifer Road
Sunnyvale, California 94086

Re: K140189
Trade/Device Name: EndoWrist® Vessel Sealer
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY, GEI
Dated: May 6, 2014
Received: May 7, 2014

Dear Ms. Nasr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140189

Device Name
EndoWrist® Vessel Sealer

Indications for Use *(Describe)*
The EndoWrist® Vessel Sealer is a bipolar electrosurgical instrument for use with the da Vinci Xi Surgical System and the ERBE VIO dV electrosurgical generator. It is intended for grasping and blunt dissection of tissue and for bipolar coagulation and mechanical transection of vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument. The EndoWrist Vessel Sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S